

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNOMEDICAL A/S,

Plaintiff,

vs.

SMITHS MEDICAL MD, INC.,

Defendant.

CASE NO. 1:09-CV-04375

Judge Blanche M. Manning
Magistrate Judge Sidney I. Schenkier

JURY TRIAL DEMANDED

**SMITHS MEDICAL ASD, INC.'S ANSWER TO UNOMEDICAL A/S'S COMPLAINT,
AMENDED DEFENSES, AND AMENDED COUNTERCLAIMS**

Smiths Medical ASD, Inc., formerly known as Smiths Medical MD, Inc. ("Smiths"), answers Unomedical A/S's ("Unomedical") Complaint as follows:

THE PARTIES

1. Unomedical is a Danish corporation with its principal place of business at Birkerød Kongevej 2, DK-3460 Birkerød, Denmark.

ANSWER: Smiths lacks sufficient knowledge or information to form a belief regarding the allegations in Paragraph 1 of the Complaint and, therefore, denies the same.

2. On information and belief, Defendant is incorporated in the State of Minnesota, with a principal place of business at 1265 Grey Fox Rd., St. Paul, Minnesota 55112

ANSWER: Denied. On July 31, 2009, Smiths Medical MD, Inc. merged with Smiths Medical ASD, Inc. The new company, Smiths Medical ASD, Inc., is a Delaware corporation with a principal place of business at 1265 Grey Fox Rd., St. Paul, Minnesota 55112.

JURISDICTION

3. This is an action for patent infringement under the patent laws of the United States for which this Court has jurisdiction under 35 U.S.C. § 271 and 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Admitted.

4. This Court has personal jurisdiction over Defendant because, on information and belief, Defendant regularly, systematically and intentionally distributes infringing products within this District. Defendant has placed and continues to place infringing products in the stream of commerce with the expectation and knowledge that such products will be and are purchased by consumers in this District.

ANSWER: Smiths admits that this Court has personal jurisdiction over Smiths. Smiths denies the remainder of the allegations in Paragraph 4, including any allegation that Smiths has committed acts of infringement.

VENUE

5. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1391(c) because, on information and belief, Defendant has committed, and continues to commit, acts of infringement in this District. Furthermore, as alleged above, Defendant regularly and systematically conducts business in this District and is subject to personal jurisdiction in this District.

ANSWER: Smiths admits that venue is proper in this District, although Smiths contends that venue is clearly more convenient in the District of Minnesota. Smiths denies the remainder

of the allegations in Paragraph 5, including any allegation that Smiths has committed acts of infringement.

COUNT ONE - INFRINGEMENT OF U.S. PATENT NO. 7,407,493

6. Unomedical incorporates by reference the allegations in Paragraphs 1-5.

ANSWER: Paragraph 6 does not include any factual allegations.

7. Unomedical is the owner of all right, title and interest in U.S. Patent No. 7,407,493 (the "'493 patent"), entitled "Container for Disposable Needle or Cannula," which is issued on August 5, 2008. A copy of the '493 patent is attached as Exhibit A.

ANSWER: Smiths admits that the face of U.S. Patent No. 7,407,493 (the "'493 patent") indicates that the '493 Patent was issued on August 5, 2008 and has the title "Container for Disposable Needle or Cannula." Smiths lacks sufficient knowledge or information to form a belief regarding the remaining allegations in Paragraph 7 of the Complaint and, therefore, denies the same.

8. Defendant has infringed and continues to directly and/or indirectly infringe and/or induces the infringement of the '493 patent under 35 U.S.C. § 271. Defendant makes, uses, sells and/or offers to sell within the United States or imports into the United States products covered by the '493 patent. These products include, but are not limited to, the CLEO® 90 Infusion Set. The instruction brochure for the CLEO® Infusion Set is attached as Exhibit B. A copy of the packaging from the CLEO® 90 Infusion Set, and the English portions of the packaging insert, are attached as Exhibit C.

ANSWER: Denied.

9. Defendant's infringement as alleged in this Complaint constitutes willful infringement on the '493 patent.

ANSWER: Denied.

10. Pursuant to 35 U.S.C. § 283, Unomedical is entitled to an injunction against further infringement of the '493 patent. If Defendant's infringing activities are not enjoined, Unomedical will suffer irreparable harm that cannot be compensated by monetary damages.

ANSWER: Denied.

11. Unomedical has suffered economic harm as a result of Defendant's infringing activities in an amount to be proven at trial.

ANSWER: Denied.

SMITHS' AMENDED AFFIRMATIVE DEFENSES

Smiths incorporates herein by reference the answers to Paragraphs 1 to 11 above and the allegations of Counterclaim Paragraphs 23-151 below for the purposes of each affirmative defense.

First Defense

12. Smiths has not directly or indirectly infringed any claim of the '493 patent.

Second Defense

13. Every asserted claim of the '493 patent is invalid, *inter alia*, because each is anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103. Specifically, prior art references exist that either fully anticipate one or more claims of the '493 patent or render one or

more claims of the '493 patent obvious in combination with other public references and/or information known to a person having skill in the art.

Third Defense

14. One or more claims of the '493 patent are invalid because they are not enabled and fail to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. The failure includes, but is not limited to, the applicant's failure to teach in the patent's specification a "medical device" left on the patient's skin, or removing a "piercing member" from the inserted cannula and the patient after insertion such that a person skilled in the art could practice the claims without undue experimentation.

Fourth Defense

15. Every asserted claim of the '493 patent is invalid and/or unenforceable for failure to comply with United States patent law, 35 U.S.C. § 1 *et seq.*

Fifth Defense

16. Unomedical has not suffered any damages as a consequence of any actions or omissions by Smiths.

Sixth Defense

17. On information and belief, Unomedical is barred, for failure to mark pursuant to 35 U.S.C. § 287, from recovery of damages for any alleged infringement of the '493 patent by Smiths occurring prior to notice of infringement.

Seventh Defense

18. On information and belief, by engaging in practices including but not limited to bad faith litigation to enforce one or more patents it knows to be invalid or not infringed for the

reasons described in Paragraphs 22 to 151 below, Unomedical has impermissibly broadened the physical and/or temporal scope of the '493 patent grant with anticompetitive effect.

19. On information and belief, each claim of the '493 patent is unenforceable at least in view of this intentional patent misuse.

Eighth Defense

20. Unomedical is estopped from construing the claims of the '493 patent to cover any Smiths product because representations, omissions, and/or concessions made during prosecution of the '493 patent and/or related U.S. or foreign patents and patent applications limit the scope of the claims of the '493 patent.

21. Prosecution history estoppel bars Unomedical from asserting infringement under the doctrine of equivalents of claims of the '493 patent and from adopting claim construction positions contrary to statements and amendments made during prosecution of the '493 patent and/or related to U.S. or foreign patents and patent applications.

Ninth Defense

22. On information and belief, the '493 patent is unenforceable pursuant to 37 C.F.R. § 1.56 and the doctrines of inequitable conduct and "fraud on the Patent Office." Specifically, on information and belief, Attorney Jane Doe ("Doe")¹ and others involved in or associated with the prosecution of the '493 patent knowingly buried material information within a large body of disclosed references and thereby hid it from the Patent Office with intent to deceive the Patent Office,² as follows:

¹ In accordance with the Federal Circuit's opinion in *Exergen Corp. v. Wal-Mart Stores*, ___ F.3d ___, 2009 U.S. App. LEXIS 17311 (Fed. Cir. 2009), Attorney Jane Doe will be identified upon leave of this Court.

² Intentional burying of relevant, material prior art reference among a multitude of less pertinent references can support a finding of inequitable conduct. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995) ("'[B]urying' a particularly material reference in a prior art statement containing a multiplicity of other references can be probative of bad faith."); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68

A. On information and belief, the '493 patent is unenforceable at least in view of Doe's knowing and intentional hiding of U.S. Pat. No. 5,451,210 ("the '210 patent") from the Patent Office during prosecution of the '493 patent.

- i. The '210 patent discloses or renders obvious every element of at least claim 1 of the '493 patent, and is therefore material to the '493 patent. See Exhibit 1.
- ii. The '210 patent issued more than eight years before the '493 patent filing date, such that it is 102(b) prior art that Unomedical cannot swear behind.
- iii. The relevant disclosure appears in the '210 patent in at least Figures 1-4 and Cols. 2, 6-7, as further detailed in Exhibit 1.
- iv. The '210 patent discloses a container for facilitating placement of a medical device through a patient's skin, the container comprising: a cylindrical housing in which there are defined a cap and a sleeve, said sleeve including a resting base having a planar surface configured for placement against a patient's skin, said cap surrounding at least a portion of said sleeve and being axially slidable relative to said sleeve to substantially encase said sleeve when a sufficient pressure is exerted on said cap; a retaining member located within said housing, said retaining member having a needle secured thereto; a releasing member for releasing said needle from said re-

F.Supp.2d 508, 545-46 (D.N.J. 1999) ("Several courts have held that burying a relevant, material prior art reference among a multitude of less pertinent references can support a finding of inequitable conduct."); *Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co., Inc.*, 837 F.Supp. 1444, 1477 (N.D. Ind. 1992) (finding inequitable conduct and holding that "it is likewise a violation of the duty of candor...to disclose a pertinent prior art reference to the examiner in such a way as to 'bury' it or its disclosures in a series of disclosures of less relevant prior art references...."); *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F. Supp. 948, 965 (S.D. Fla. 1972), *aff'd*, 479 F.2d 1328 (5th Cir.), *cert. denied*, 414 U.S. 874 (1973) (finding inequitable conduct and holding that "the purpose of th[e] misrepresentation was to bury the [material] patent in a long list of allegedly old prior art patents....Such conduct clearly violates the required standard of candor and fair dealing with the Patent Office.").

taining member when said cap is made to slide on said sleeve, thereby allowing the placement of said needle under the patient's skin and the subsequent removal of said container; wherein the container is disposable and upon exertion of said pressure on said cap the force resulting from said pressure is transferred to said needle so that said needle is placed through the patient's skin by means of said pressure exerted on said cap. See Exhibit 1. The '210 patent disclosure not cumulative to the prior art of record.

- v. Doe was aware of the '210 patent and its materiality, because Doe disclosed the '210 patent, albeit buried amongst the 460 other references Doe disclosed.

B. On information and belief, the '493 patent is unenforceable at least in view of Doe's knowing and intentional hiding of U.S. Pat. No. 5,248,301 ("the '301 patent") from the Patent Office during prosecution of the '493 patent.

- i. The '301 patent discloses or renders obvious every element of at least claim 23 of the '493 patent, and is therefore material to the '493 patent. See Exhibit 1.
- ii. The '301 patent issued more than ten years before the '493 patent filing date, such that it is 102(b) prior art that Unomedical cannot swear behind.
- iii. The relevant disclosure appears in the '301 patent in at least Figs. 2-9, and Cols. 3, 5-9, as further detailed in Exhibit 1.
- iv. The '301 patent discloses a container for facilitating placement of a cannula of a medical device through a patient's skin, the container compris-

ing: a housing comprising a cap telescopically slidable over a sleeve, said sleeve defining an axis therethrough and including a resting base configured for placement against said patient's skin, said cap being slidable between a first position and a second position along the axis of said sleeve, wherein said cap substantially encases the axial length of said sleeve when said cap is in said second position; and a retaining member located within said housing, said retaining member having a piercing member secured thereto, said piercing member extending at least partially through said cannula for transcutaneous placement of said cannula; wherein said piercing member is concealed within said sleeve when said cap is in said first position and exposed from said sleeve when said cap is in said second position; wherein upon exertion of said pressure on said cap, said cap slides axially toward said patient's skin along said sleeve so that said piercing member is placed through said patient's skin and an end of said cannula is transcutaneously inserted and said medical device is retained on the patient and said piercing member secured to said retaining member is removed. See Exhibit 1. The '301 patent disclosure not cumulative to the prior art of record.

- v. Doe was aware of the '301 patent and its materiality, because Doe disclosed the '301 patent, albeit buried amongst the 460 other references Doe disclosed.

- C. On information and belief, the '493 patent is unenforceable at least in view of Doe's knowing and intentional hiding of U.S. Pat. No. 6,613,064 ("the '064 patent") from the Patent Office during prosecution of the '493 patent.
- i. The '064 patent discloses or renders obvious every element of at least claim 1 of the '493 patent, and is therefore material to the '493 patent. See Exhibit 1.
 - ii. The '064 patent issued from U.S. Patent App. No. 2001/0039387 ("the '387 application").
 - iii. The '387 application has the same disclosure as the '064 patent and was published more than two years before the '493 patent filing date, such that it is 102(b) prior art that Unomedical cannot swear behind.
 - iv. The relevant disclosure appears in the '064 patent in at least Figs 1 and 4, as described in Columns 1 and 2. See Exhibit 1.
 - v. The '064 patent discloses a cap that is axially slidable toward the base and the cap substantially encases the sleeve when a sufficient pressure is exerted on the cap. The '064 patent disclosure not cumulative to the prior art of record.
 - vi. Doe was aware of the '064 patent and its materiality, because Doe disclosed the '064 patent, albeit buried amongst the 460 other references Doe disclosed.
- D. During prosecution of the '493 patent, Doe disclosed 461 references to the examiner. Given the unusually large number of disclosed references, on the examiner made an explicit request in an office action mailed December 11, 2006 that appli-

cant "point out any particular references in the IDS which they belief may be of particular relevance to the instant claimed invention." Doe did not respond to this request. On information and belief, Doe intended to mislead the Patent Office by burying the material, non-cumulative '210, '301, and '064 patents within the 461 disclosed references and failing to respond to the examiner's direct, written request to identify references of particular relevance.

SMITHS' AMENDED COUNTERCLAIMS

Counter-Plaintiff Smiths hereby brings these counterclaims against Counter-Defendant Unomedical for declaratory judgment of noninfringement and invalidity of patents; and also for damages and injunctive relief for tortious interference with prospective business relations, unfair competition in violation of the Lanham Act and Minnesota's Uniform Deceptive Trade Practices Act, and federal and state law antitrust violations.

23. Counter-Plaintiff Smiths is a Delaware corporation, with a principal place of business at 1265 Grey Fox Rd., St. Paul, Minnesota 55112.

24. Counter-Defendant Unomedical claims it is a Danish corporation with its principal place of business at Birkerød Kongevej 2, DK-3460 Birkerød, Denmark.

25. These are counterclaims for a declaratory judgment of noninfringement and invalidity of patents arising under the Declaratory Judgment Act, specifically, 28 U.S.C. §§ 2201 and 2202, and the Patent Act, 35 U.S.C. § 100, *et seq.*; for tortious interference with prospective business relations; for unfair competition under the Lanham Act, specifically 15 U.S.C. §1125; for unfair competition under the Minnesota Uniform Deceptive Trade Practices Act MINN. STAT. § 325D.43 *et seq.*; and for damages and an injunction for violations of the Sherman Antitrust Act, 15 U.S.C. §§ 1, 2 *et seq.*, the Clayton Act, 15 U.S.C. §§ 15 and 26 and the Minnesota Antitrust Law of 1971, MINN. STAT. § 325D.49 *et seq.*

26. Subject matter jurisdiction in this Court is proper pursuant to 28 U.S.C. §§ 1331 (federal question), 1337(a) (antitrust), 1338(a) (patents), 1338(b) (unfair competition joined with a patent claim), 1367 (supplemental jurisdiction), 2201(a) (declaratory judgment) and 15 U.S.C. §§ 4 (antitrust), 15 (antitrust), 1121 (Lanham act).

27. This Court has personal jurisdiction over Unomedical because Unomedical has availed itself of this Court.

28. Venue is proper in this Court under 28 U.S.C. § 1391(d) and under 15 U.S.C. § 22, because Unomedical is an alien corporation or can be found or is transacting business in this District and because Unomedical's wrongful conduct, in part, has occurred in this District. Venue is also proper in this Court because Unomedical has availed itself of this Court.

29. The patent asserted against Smiths in this case is U.S. Patent No. 7,407,493 (the "'493 patent").

COUNTERCLAIM COUNT I
Invalidity of the '493 Patent

30. Smiths realleges and incorporates herein by reference Paragraphs 1-29.

31. In Paragraphs 8-11 of its Complaint, Unomedical has made general allegations that the '493 patent is infringed by Counter-Plaintiff through the manufacture, use, sale or offer for sale of products such as the CLEO® Infusion Set.

32. Unomedical's actions and allegations have created a case or controversy between Smiths and Unomedical.

33. Each asserted claim of the '493 patent is invalid, *inter alia*, for at least one of the following reasons: failure to comply with United States patent law, 35 U.S.C. § 1 *et seq.*; failure to claim patentable subject matter under 35 U.S.C. § 101; anticipation under 35 U.S.C. § 102;

obviousness under 35 U.S.C. § 103; failure of the specification to comply with 35 U.S.C. § 112; and/or failure to comply with one or more of the requirements of 35 U.S.C. § 112.

34. Smiths is entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that each asserted claim of the '493 patent is invalid.

COUNTERCLAIM COUNT II
Noninfringement of the '493 Patent

35. Smiths realleges and incorporates herein by reference Paragraphs 1-34.

36. Smiths' products lack one or more limitation of any valid claim, both literally and by equivalence (including under the doctrine of prosecution history estoppel).

37. Smiths is entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that their accused products do not infringe any valid claims of the '493 patent.

COUNTERCLAIM COUNT III
Tortious Interference with Prospective Economic Advantage

38. Smiths realleges and incorporates herein by reference Paragraphs 1-37.

39. Smiths had a reasonable expectation of entering into valid business relationships involving its CLEO® products, product lines, and/or other business assets.

40. Unomedical knew of this expectancy.

41. On information and belief, Unomedical has intentionally and wrongfully interfered with Smiths' ability to enter into contracts or business relationships with third parties interested in purchasing Smiths' products, product lines, and/or other business assets by, *inter alia*:

a. Making false statements to such third parties to the effect that Smiths' products infringe the '493 patent;

b. Amending pending patent claims to cover Smiths' existing products, knowing that the claims were unsupported by their associated specification; and/or

c. Trying to improperly direct Smiths' sale of certain products and/or product lines to or away from certain prospective purchasers.

42. On information and belief, those false statements were made, or other actions taken, in bad faith because Unomedical knew that the '493 patent was invalid, unenforceable, and/or not infringed by Smiths.

43. The infusion set inserter market is consumer-facing and has a powerful, if informal, communication network. Unomedical knew of the power of this network and used word-of-mouth disparagement to advance its interference with Smiths' business.

44. There is a reasonable probability that, but for Unomedical's conduct, Smiths would have realized certain business expectations known to Unomedical.

45. Smiths has been damaged as a result of Unomedical's wrongful interference.

46. Smiths is entitled to monetary damages as a result of Unomedical's tortious interference with Smiths' prospective business relations.

COUNTERCLAIM COUNT IV
Violation of the Lanham Act

47. Smiths realleges and incorporates herein by reference Paragraphs 1-46.

48. On information and belief, Unomedical has made false statements in advertising or promotion distributed in interstate commerce, to the effect that Smiths' products infringe the '493 patent.

49. On information and belief, these false statements were made in bad faith because Unomedical knew that the '493 patent was invalid, unenforceable, and/or not infringed by Smiths.

50. On information and belief, these false statements have actually deceived or are likely to deceive a substantial segment of the intended audience.

51. On information and belief, the false statements were material because they were likely to influence purchasing decisions.

52. On information and belief, these false statements related to goods entering into interstate commerce.

53. Smiths has been or is likely to be damaged by Unomedical's false, bad-faith statements in violation of 15 U.S.C. §1125(a).

54. Smiths is entitled to remedies including an injunction barring Unomedical from making further false statements in connection with any advertising or promotion and monetary damages including disgorgement of Unomedical's profits and fees.

COUNTERCLAIM COUNT V
Violation of the Minnesota Deceptive Trade Practices Act

55. Smiths realleges and incorporates herein by reference Paragraphs 1-54.

56. On information and belief, Unomedical's false statements to the effect that Smiths' products infringe the '493 patent were made in the course of its business, vocation or occupation.

57. On information and belief, these false statements related directly to Smiths' business or goods.

58. Smiths has been or is likely to be damaged by Unomedical's false, bad-faith statements in violation of MINN. STAT. § 325D.44.

59. Smiths is entitled to remedies including an injunction barring Unomedical from making further false statements in connection with any advertising or promotion and monetary damages including disgorgement of Unomedical's profits and fees.

COUNTERCLAIM COUNT VI
Sherman Act § 2, Monopolization

60. Smiths realleges and incorporates herein by reference Paragraphs 1-59.

61. The Sixth and Seventh Counterclaims are based on Unomedical's repeated abuse of its substantial market power in Product and Technology Markets described below and the direct and substantial injury to Counter-Plaintiff resulting from Unomedical's anticompetitive conduct. Unomedical would not have its substantial market power in these Markets but for its exclusionary conduct, including but not limited to assertion of patent claims it knows to be invalid, unenforceable, and/or not infringed, and the objectively baseless and sham litigation it has pursued in the United States.

62. Because Unomedical knows the '493 patent to be invalid, unenforceable, and/or not infringed, its allegations and claims in this action are brought in bad faith, are objectively baseless and a sham, and are motivated by Unomedical's desire to impose collateral, anti-competitive injury rather than to obtain a justifiable legal remedy.

63. Unomedical has knowingly and willfully asserted the '493 patent against Smiths in this case.

64. On information and belief, by at least early 2004 Unomedical learned of the CLEO® product, and by at least late 2004 knew of its public sales.

65. On information and belief Unomedical procured rights to the '493 patent application from the original assignee (Cané S.R.L.) and recorded the assignment of that application to Unomedical on February 8, 2005.

66. On information and belief, Unomedical believed competing fairly in the market with the CLEO® product line would damage Unomedical's business.

67. On October 25, 2006, Unomedical amended its '493 patent application to add issued claims 23 through 35, more than a year after Smiths publicly disclosed the accused CLEO® product in late 2004.

68. On information and belief, Unomedical knowingly drafted claims 23 through 35 in an attempt to have those claims read onto the accused CLEO® product, despite the fact that claims 23 through 35 are not enabled and do not comply with the written description requirement under 35 U.S.C. §112, first paragraph because, for example, the '493 patent specification discloses embodiments that particularly teach the removal of the piercing member from the retaining member such that the piercing member remains in the patient's skin, but fails to have disclosure sufficient to enable a person skilled in the art to practice, without undue experimentation, the removal of the needle from the patient as required by claims 23 through 35.

69. On information and belief, Unomedical knew at the time the '493 patent issued that at least claims 23 through 35 were invalid for failure to comply with 35 U.S.C. § 112.

70. On information and belief, Unomedical now knows that at least claims 23 through 35 of the '493 patent are invalid for failure to comply with 35 U.S.C. § 112.

71. On information and belief, Unomedical knows that the accused CLEO® product cannot infringe any valid, enforceable claim either literally or under the doctrine of equivalents because the CLEO® product facially lacks one or more limitation of those claims.

72. During prosecution of the '493 patent Unomedical disclosed 461 references to the Examiner.

73. During prosecution of the '493 patent, the examiner requested that the applicant identify any particularly material references out of the 383 references submitted in the first Information Disclosure Statement. Neither Unomedical nor those associated with the prosecution of the '493 patent responded to that request.

74. On information and belief, and as specifically plead in paragraph 22 (Smiths' Ninth Affirmative Defense) above, Unomedical and/or those associated with the prosecution of

the '493 patent buried material references (including but not limited to U.S. Patent Nos. 5,451,210, 5,248,301, and 6,613,064) within the large number of disclosed references with an intent to deceive the Patent Office.

75. On information and belief, the '493 patent is unenforceable at least in view of Doe's knowing and intentional hiding of U.S. Pat. No. 5,451,210 ("the '210 patent) from the Patent Office during prosecution of the '493 patent.

76. The '210 patent discloses or renders obvious every element of at least claim 1 of the '493 patent.

77. The '210 patent was material to the '493 patent prosecution.

78. The '210 patent issued more than eight years before the '493 patent filing date, such that it is 102(b) prior art that Unomedical cannot swear behind.

79. The relevant disclosure appears in the '210 patent in at least Figures 1-4 and Cols. 2, 6-7, as further detailed in Exhibit 1.

80. The '210 patent discloses a container for facilitating placement of a medical device through a patient's skin, the container comprising: a cylindrical housing in which there are defined a cap and a sleeve, said sleeve including a resting base having a planar surface configured for placement against a patient's skin, said cap surrounding at least a portion of said sleeve and being axially slidable relative to said sleeve to substantially encase said sleeve when a sufficient pressure is exerted on said cap; a retaining member located within said housing, said retaining member having a needle secured thereto; a releasing member for releasing said needle from said retaining member when said cap is made to slide on said sleeve, thereby allowing the placement of said needle under the patient's skin and the subsequent removal of said container; wherein the container is disposable and upon exertion of said pressure on said cap the force re-

sulting from said pressure is transferred to said needle so that said needle is placed through the patient's skin by means of said pressure exerted on said cap. See Exhibit 1.

81. The '210 patent disclosure not cumulative to the prior art of record.

82. Doe was aware of the '210 patent and its materiality.

83. On information and belief, the '493 patent is unenforceable at least in view of Doe's knowing and intentional hiding of U.S. Pat. No. 5,248,301 ("the '301 patent") from the Patent Office during prosecution of the '493 patent.

84. The '301 patent discloses or renders obvious every element of at least claim 23 of the '493 patent. See Exhibit 1.

85. The '301 patent was material to the '493 patent prosecution.

86. The '301 patent issued more than ten years before the '493 patent filing date, such that it is 102(b) prior art that Unomedical cannot swear behind.

87. The relevant disclosure appears in the '301 patent in at least Figs. 2-9, and Cols. 3, 5-9, as further detailed in Exhibit 1.

88. The '301 patent discloses a container for facilitating placement of a cannula of a medical device through a patient's skin, the container comprising: a housing comprising a cap telescopically slidable over a sleeve, said sleeve defining an axis therethrough and including a resting base configured for placement against said patient's skin, said cap being slidable between a first position and a second position along the axis of said sleeve, wherein said cap substantially encases the axial length of said sleeve when said cap is in said second position; and a retaining member located within said housing, said retaining member having a piercing member secured thereto, said piercing member extending at least partially through said cannula for transcutaneous placement of said cannula; wherein said piercing member is concealed within said sleeve when

said cap is in said first position and exposed from said sleeve when said cap is in said second position; wherein upon exertion of said pressure on said cap, said cap slides axially toward said patient's skin along said sleeve so that said piercing member is placed through said patient's skin and an end of said cannula is transcutaneously inserted and said medical device is retained on the patient and said piercing member secured to said retaining member is removed. See Exhibit 1.

89. The '301 patent disclosure not cumulative to the prior art of record.

90. Doe was aware of the '301 patent and its materiality.

91. On information and belief, the '493 patent is unenforceable at least in view of Doe's knowing and intentional hiding of U.S. Pat. No. 6,613,064 ("the '064 patent) from the Patent Office during prosecution of the '493 patent.

92. The '064 patent discloses or renders obvious every element of at least claim 1 of the '493 patent. See Exhibit 1.

93. The '064 patent was material to the '493 patent prosecution.

94. The '064 patent issued from U.S. Patent App. No. 2001/0039387 ("the '387 application).

95. The '387 application has the same disclosure as the '064 patent and was published more than two years before the '493 patent filing date, such that it is 102(b) prior art that Unomedical cannot swear behind.

96. The relevant disclosure appears in the '064 patent in at least Figs 1 and 4, as described in Columns 1 and 2. See Exhibit 1.

97. The '064 patent discloses a cap that is axially slidable toward the base and the cap substantially encases the sleeve when a sufficient pressure is exerted on the cap.

98. The '064 patent disclosure not cumulative to the prior art of record.

99. Doe was aware of the '064 patent and its materiality.

100. During prosecution of the '493 patent, Doe disclosed 461 references to the examiner.

101. The examiner made an explicit request in an office action mailed December 11, 2006 that applicant "point out any particular references in the IDS which they belief may be of particular relevance to the instant claimed invention." Doe did not respond to this request.

102. On information and belief, Doe intended to mislead the Patent Office by burying the material, non-cumulative '210, '301, and '064 patents within the 461 disclosed references and failing to respond to the examiner's direct, written request to identify references of particular relevance.

103. On information and belief, Unomedical's inclusion of the published version of the '493 patent application itself (U.S. Pat. App. No. 2005/0035014) and other similarly non-material references evidences Unomedical's bad-faith, deceptive burying of material references.

104. On information and belief, Unomedical and/or those associated with the prosecution of the '493 patent knowingly withheld at least one or more of U.S. Pat. App. No. 2001/0039387, U.S. Pat. No. 5,135,502, and U.S. Pat. No. 4,378,015 from the examiner during prosecution of the '493 patent.

105. On information and belief, Unomedical and/or those associated with the prosecution of the '493 patent withheld at least one or more of U.S. Pat. App. No. 2001/0039387 and U.S. Pat. No. 4,378,015 from the examiner during prosecution of the '493 patent with an intent to deceive the Patent Office.

106. U.S. Pat. App. No. 2001/0039387 was material to the '493 patent prosecution.

107. U.S. Pat. No. 4,378,015 was material to the '493 patent prosecution.

108. U.S. Pat. App. No. 2001/0039387 is not cumulative to any other reference before the examiner during the '493 patent prosecution.

109. U.S. Pat. No. 4,378,015 is not cumulative to any other reference before the examiner during the '493 patent prosecution.

110. Because Unomedical knows the '493 patent to be invalid, unenforceable, and/or not infringed by Smiths, Unomedical's litigation against Smiths is objectively baseless (because it is premised upon a patent that is invalid, obtained through misrepresentations and fraud, and/or not infringed) and a sham.

111. One relevant product market consists of integrated infusion set inserters wherein the infusion set and inserter are integrated into a single unit (hereinafter "Integrated Infusion Sets") that are marketed or sold in the United States (the "Product Market" or the "Products"). On information and belief, Unomedical claims there are no reasonably interchangeable products that can compete against the Products. The United States is the relevant geographic market for the Product Market. Alternatively, the relevant geographic market for such Products is world-wide. For example, for Products that are designed for sale in the United States but also sold in other countries, Smiths has suffered antitrust injury from Unomedical's illegal conduct both in the United States and in other geographic areas in which the same or similar products are also sold.

112. The Product Market for Integrated Infusion Sets is distinct and includes Products that integrate the infusion set and the inserting device into one unit. These Integrated Infusion Sets have an advantage over infusion sets that must be manually inserted or that are separate from the inserting device because the Integrated Infusion Sets allow the infusion set to be in-

serted more easily by children and non-professionals without assistance, are highly portable, can decrease pain associated with insertion, and maintain better sterility.

113. On information and belief, Unomedical has at least a 75% market share just in the manufacture and sale of such Integrated Infusion Sets but also claims the power to exclude all other competitors in such a Product Market in the United States. Thus, Unomedical claims it has power to exclude (and hence market power over) 100% of the Product Market.

114. Smiths does not agree that Unomedical has the legal right to exclude Smiths from the Product Market, yet Smiths has achieved less than 25% of said Market, leaving Unomedical with at least a 75% market share. Even if the court were to find that Unomedical lacks the legal power to exclude other competitors in the Product Market, its monopolistic conduct has harmed competition significantly, already directly injured Smiths by causing a loss of sales and penetration in the Product Market, and has excluded Smiths and others from competing effectively in the Product and Technology Markets.

115. Another relevant product market consists of both the technology claimed in the '493 patent and any competitive alternative technologies that enable manufacturers to design or make Integrated Infusion Sets that are marketed or sold in the United States without practicing the technology claimed in the '493 patent (collectively, the "Technology Market" or the "Technology"). On information and belief, Unomedical claims there are no reasonably interchangeable technologies that can compete against the Technology. The relevant geographic market for such Technology is worldwide. Alternatively, the United States is the relevant geographic market for the Technology Market.

116. Unomedical claims that it has the power to exclude through the '493 patent all competition in what had been defined herein as the Technology Market, and thus Unomedical claims a 100% market share in the Technology Market.

117. Smiths does not agree that Smiths' own competing technology is covered by Unomedical's '493 patent. Unomedical has at least 75% of the market share in the Technology Market.

118. Unomedical's market power, however, has also substantially affected Smiths' small percentage of the Technology Market and thus demonstrates that Unomedical's market power is substantial.

119. Even if Unomedical's patents are ultimately proven to be unenforceable or invalid, its monopolistic conduct has already directly injured Smiths by causing a loss of sales and penetration in the Technology Market and other costs in defending against Unomedical's conduct.

120. Prior to filing its Complaint in this suit, Unomedical told Smiths' customers and prospective customers, including at least Tandem Diabetes Care, that Smiths' products infringe one or more valid Unomedical patents.

121. On information and belief, Unomedical made such statements in order to maintain its monopoly power in the Product and Technology Markets, and to influence Smiths' customers to purchase Unomedical products in place of Smiths' and/or not to do business with Smiths.

122. On information and belief, Unomedical knew such statements to be false.

123. Unomedical's statements to Smiths' customers, including false allegations of infringement, have raised Smiths' marginal costs by requiring Smiths to undertake the expense and effort to refute such statements and threaten Smiths' viability in the marketplace.

124. On information and belief, Unomedical's anticompetitive conduct has unlawfully restrained output in the Product Market and has caused injury to Smiths by adversely affecting prices in that Market.

125. In both the Product and Technology Markets, on information and belief, Unomedical has through its illegal conduct demonstrated market power to restrain output, exclude competition, and raise or maintain market prices above competitive levels. Unomedical has already demonstrated its market power by excluding Smiths and others from substantial portions of the Markets at issue in this Counterclaim.

126. On information and belief, Unomedical has demonstrated a specific intent to monopolize the Product and Technology Markets, in part, by pursuing objectively baseless and sham litigation in the Northern District of Illinois against Smiths, who is Unomedical's primary competitor in those Markets.

127. On information and belief, if Unomedical successfully drives its competitors from the market via invalid and/or fraudulently obtained patents and objectively baseless sham litigation, it will unilaterally set or maintain prices substantially above competitive levels for the foreseeable future.

128. On information and belief, Unomedical's monopolistic conduct has already kept prices for both the Technology and the Products above competitive levels through its unlawful restraint of output in the Product and Technology Markets. Moreover, Unomedical's unlawful conduct has the effect of reducing innovation and choice in both Markets to the detriment of competition and consumers.

129. On information and belief, Unomedical's anticompetitive conduct has raised rivals' costs and created significant barriers to entry into the Product and Technology Markets, and

has excluded competition, restrained output, and adversely affected price and innovation in both Markets.

130. On information and belief, the Product and Technology Markets are highly-concentrated and, due to Unomedical's conduct, have barriers to entry which would prevent new competition from entering for at least two years, if not more, even if prices in the Markets were raised substantially.

131. Additional barriers to entry to the Product and Technology Markets arise from the highly-regulated nature of the medical device industry as a whole, including the requirement of FDA approval before a device can be introduced to the market, and, on information and belief, Unomedical's anticompetitive conduct has exacerbated these additional barriers to entry.

132. On information and belief, Unomedical's claims in this action constitute unfair, predatory, and anti-competitive tactics that have no legitimate business or efficiency justification. On information and belief, Unomedical's conduct thus has no legitimate, pro-competitive justification or any justification that would outweigh its anti-competitive effects.

133. Unomedical's conduct has and will continue to directly and substantially affect interstate commerce in the United States. Moreover, Unomedical's illegal conduct, described herein, has directly, substantially, and foreseeably restrained interstate commerce.

134. On information and belief, Unomedical's anticompetitive conduct has and will directly and proximately cause antitrust injury to Counter-Plaintiff within the Product and Technology Markets, including but not limited to causing substantial injury to competition, and hence consumers and competitors (including Counter-Plaintiff) in the Markets. Consumers of these Markets include the end-use purchasers of devices using the Products, as well as the manufacturers, sellers, and retailers of such devices.

135. Smiths has directly and proximately suffered injury as a result of Unomedical's Anticompetitive Conduct. Specifically, Smiths' sales of products to companies that participate in the Product or Technology Markets (either as manufacturers, purchasers or sellers) have been impaired and Smiths cannot itself freely participate directly in these Markets.

136. The damages and injuries that Smiths has sustained because of Unomedical's anti-trust violations are direct and unique, and are not duplicative or derivative of any injuries suffered by any other participant in any market alleged herein. Indeed, Smiths' damages and injuries flow directly and specifically from Unomedical's wrongful, exclusionary acts that make Unomedical's conduct unlawful.

137. Smiths' antitrust injury is of the type the antitrust laws were intended to prevent because it is a direct result of Unomedical's anti-competitive conduct, alleged herein, which occurred within the United States and because Unomedical's anti-competitive conduct has led to higher prices and fewer alternatives. The harm and lost profits to Smiths from Unomedical's illegal conduct are ongoing and cumulative, and, because they substantially and adversely affect the good will of Smiths with its customers and in the Markets, cannot be relieved via monetary compensation, leaving Smiths no adequate remedy at law and, in large measure, irreparable harm. The nature of the injury is direct and not speculative, and the amount of such injury is substantial. The balance of the equities and the public interest in supporting competition in the alleged Markets weigh in favor of equitable relief in this case as well as substantial damages for those injuries that can be determined with reasonable certainty.

138. Smiths is in the best position to vindicate the public interest in antitrust enforcement.

COUNTERCLAIM COUNT VII
Sherman Act § 2 Attempt to Monopolize

139. Smiths realleges and incorporates herein by reference Paragraphs 1-138.

140. On information and belief, and in the alternative, through the conduct alleged in Paragraphs 12 through 139 above, Unomedical has a dangerous probability of achieving illegal, monopoly power (the power to exclude competition and raise prices) in the alleged Markets and has been and continues to attempt to monopolize the Product and Technology Markets with specific intent to monopolize each Market.

141. On information and belief, Unomedical's greater than 65% Product Market share, and the claimed 100% market share over the Technology, together with the unlawful conduct alleged herein, demonstrates that Unomedical, if it has not already done so, is dangerously close to acquiring monopoly power in the Product and Technology Markets.

142. Smiths has directly and proximately suffered injury as a result of Unomedical's Anticompetitive Conduct. Specifically, Smiths' ability to sell its Products to companies that participate in the Product or Technology Markets has been impaired, Smiths cannot itself freely participate directly in the Markets.

143. As a direct consequence of Unomedical's alleged conduct, Smiths has lost sales and will continue to lose sales of the Products or devices including the Products and/or will continue to lose share in the Technology Market as well.

144. Unomedical's unlawful conduct under this Count has caused the same damage to competition, consumers, and competitors (e.g., Smiths), and the same adverse effect on output, innovation and competition in the relevant Markets as is alleged in the Sixth Counterclaim for Monopolization above.

COUNTERCLAIM COUNT VIII

Minnesota Antitrust Law Monopolization and Attempt to Monopolize

145. Smiths realleges and incorporates herein by reference Paragraphs 1-144.

146. On information and belief, Unomedical's anticompetitive conduct constitutes an illegal establishment, maintenance, or use of monopoly power and/or an illegal attempt to achieve same under the Minnesota Antitrust Law of 1971, MINN. STAT. § 325D.49 *et seq.*

147. On information and belief, Unomedical does business in the state of Minnesota.

148. On information and belief, Unomedical's anticompetitive conduct is affects the trade and/or commerce of the state of Minnesota.

149. On information and belief, Unomedical has at least violated § 325D.52 of the Minnesota Antitrust Law of 1971.

150. Smiths has sustained and will continue to sustain injury and damages resulting in immediate and irreparable harm as a result of Unomedical's anticompetitive conduct in Minnesota and elsewhere insofar as that anticompetitive conduct affects trade or commerce in Minnesota. No remedy at law could adequately compensate Smiths for such harm, and Smiths will continue to sustain such injury and damages unless Unomedical is enjoined from continuing its anticompetitive conduct.

151. Unomedical's anticompetitive conduct in Minnesota and elsewhere has caused Smiths injury in fact and financial harm.

DEMAND FOR JURY TRIAL

152. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Defendant and Counter-Plaintiff Smiths demands a trial by jury of this action and all claims, defenses, and counterclaims so triable.

PRAYER FOR RELIEF

Wherefore, Smiths respectfully prays that:

- a. The Complaint be dismissed with prejudice;
- b. This Court adjudge, declare, and decree that all of the claims of the '493 patent are invalid, unenforceable, and have not been infringed by Smiths;
- c. This Court issue judgment declaring this case to be exceptional in favor of Smiths under 35 U.S.C. § 285, and awarding to Smiths its reasonable attorneys' fees and other expenses incurred in connection with this action;
- d. This Court issue judgment awarding to Smiths its costs of suit incurred in this action;
- e. This Court issue judgment awarding Smiths its actual damages resulting from Unomedical's tortious interference with Smiths' prospective business relations;
- f. This Court enjoin Unomedical from violating the Lanham Act by making any false or misleading representations with regard to its own or any Smiths products;
- g. This Court issue judgment awarding to Smiths damages and disgorgement of Unomedical's profits relating to such violations of the Lanham Act;
- h. This Court issue judgment declaring this case to be exceptional in favor of Smiths under 55 U.S.C. § 1117(a), and awarding to Smiths its reasonable attorneys' fees incurred in connection with this action;
- i. This Court issue judgment awarding to Smiths monetary damages related to Unomedical's violations of the Minnesota Deceptive Trade Practices Act, in-

cluding disgorgement of Unomedical's profits related to such violations and attorneys fees;

- j. This Court issue judgment permanently enjoining the conduct constituting Unomedical's violations of the Minnesota Deceptive Trade Practices Act;
- k. This Court enjoin Unomedical from violating the Sherman Act in either the Product or Technology Markets and from taking any action to enforce any patent in either Market against any participant in the Markets including competitors, customers or consumers;
- l. This Court issue judgment awarding to Smiths attorneys' fees and damages, including treble damages from lost profits and value of its business damaged as a result of Unomedical's antitrust violations;
- m. This Court issue judgment awarding to Smiths treble damages for Unomedical's violations of the Minnesota Antitrust Law of 1971;
- n. This Court issue judgment permanently enjoining the conduct constituting Unomedical's violations of the Minnesota Antitrust Law of 1971; and
- o. This Court grant Smiths such other further relief to which it may be entitled.

Dated: August 24, 2009

Respectfully submitted,

By: /s/ Barry F. Irwin, P.C.

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CERTIFICATE OF SERVICE

I hereby certify that on **August 24, 2009** I caused a true and correct copy of the foregoing document, **SMITHS MEDICAL ASD, INC.'S ANSWER TO UNOMEDICAL A/S'S COMPLAINT, AMENDED DEFENSES, AND AMENDED COUNTERCLAIMS**, was electronically filed with the Clerk of the Court using the CM/ECF system, which will send a notification of electronic filing to the counsel of record listed below that such filing is available for viewing and downloading. Documents required to be served by Fed.R.Civ.P. 5(a) have been served.

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Dated: August 24, 2009

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